

### **REMARKS**

Claims 1, 11-13, 15-22, 24, and 27-31 are pending. Claims 27 and 29 have been cancelled without prejudice to or disclaimer of the underlying subject matter. No new matter enters by way of these amendments. Upon entry of the foregoing amendment, claims 1, 11-13, 15-22, 24, 28, and 30-31 will be pending.

#### **I. Objections to the Claims**

Claims 27 and 29 have been objected to under 37 C.F.R. § 1.75(c) as being “of improper dependent form for failing to further limit the subject matter of a previous claim.” Office Action at page 2. The Examiner alleges that “[c]laims 27 and 29 depend, respectively, from claims 26 and 10, which are cancelled.” *Id.* Applicants note that claims 27 and 29 have been cancelled without prejudice to or disclaimer of the underlying subject matter. As such, the objections to claims 27 and 29 are moot and Applicants respectfully request reconsideration and withdrawal of the objections.

#### **II. Rejection under 35 U.S.C. §101**

Claims 1, 11-13, 15-22, 24, and 27-31 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific, substantial, and credible utility or a well-established utility. The Examiner states that “[f]or the same reasons as those set forth in at least the Office Actions mailed 4/12/04 and 12/2/04, the examiner maintains that [the disclosed uses] are not specific, substantial and credible for the nucleic acid sequences recited in

the instant claims.” Office Action at page 2. Applicants respectfully traverse this rejection as it applies to the amended claims.

The “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form.” *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). As previously argued, Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use to encode maize or soybean phosphogluconate pathway enzymes or fragments thereof. *See, e.g.* Specification at page 14, line 2 through page 15, line 2 and page 224, Table A. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit.

The “threshold for utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

The courts have expressed a test for utility that hinges on whether an invention provides an “identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an “identifiable benefit” may be broken into two

prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or “substantial” benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be “totally incapable of achieving a useful result,” *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, -- F.3d --, 2005 WL 2139421 (Fed. Cir, September 7, 2005). First, the Court indicated that the specification disclose “that an invention is useful to the public as disclosed in its current form.” *Id.* Second, the Court further noted that the specification “also show that that claimed invention can be used to provide a well-defined and particular benefit.” *Id.* Applicants have provided nucleic acid sequences which are shown in the specification to correlate to underlying genes of a known function, proteins involved in the phosphogluconate pathway. Such a correlation is sufficient to satisfy the utility standard. *Id.*

Applicants maintain that the present specification discloses specific and substantial uses for the claimed nucleic acid molecules, including use to encode recited maize or soybean phosphogluconate pathway enzymes or fragments thereof (*see, e.g.*, specification at page 14, line 2 through page 15, line 2, page 222, line 8 through page 223, line 13 (Example 4), Table A and the sequence listing); use to identify polymorphisms related to the recited phosphogluconate pathway enzyme (*see, e.g.*, specification at page 67, line 3 through page 74, line 18); use to

transform plants (*see, e.g.*, specification at page 92, line 1 through page 110, line 16); to determine the level or pattern of expression of a phosphogluconate pathway protein or mRNA associated with that nucleic acid molecule (*see, e.g.*, specification at page 80, line 6 through page 85, line 5); and use to overexpress or suppress the respective phosphogluconate pathway enzyme (*see, e.g.*, specification at page 110, line 12 through page 113, line 4).

The specification clearly asserts that the nucleic acid molecules of the present invention correlate to underlying proteins that encode discrete phosphogluconate pathway enzymes or fragments thereof, for example, SEQ ID NO: 1, glucose-6-phosphate-1-dehydrogenase, SEQ ID NO: 225, D-ribulose-5-phosphate-3-epimerase; and SEQ ID NO: 619 to encode phosphoglucoisomerase. *See, e.g.*, specification at page 14, line 2 through page 15, line 2, page 222, line 8 through page 223, line 13 (Example 4), Table A and the sequence listing. The specification also explains the interrelationship of the respective enzymes involved in the phosphogluconate pathway (*see, e.g.*, specification at page 1, line 17 through page 4, line 20). In addition, the specification also discloses the methods used to analyze each of the claimed nucleic acid molecules and its association with the phosphogluconate pathway. *See, e.g.*, specification at page 15, line 21 through page 20, line 4 and Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to encode the respective maize or soybean phosphogluconate pathway enzymes upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues that “[f]or the nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established.” Office

Action at page 3. As discussed above, the specification discloses that the claimed nucleic acid molecules encode proteins with significant sequence homology to recited enzymes involved in the phosphogluconate pathway. *See, e.g.*, specification at page 224, *et seq.* (Table A). The specification also discloses that the functions of phosphogluconate pathway enzymes are well-known in the art. *See, e.g.* specification at page 1, line 18 through page 4, line 20. These uses give a firm indication of the precise uses to which the claimed nucleic acid molecules can be put. *See, e.g. In re Fisher*, slip op. at 21.

The Examiner also maintains that the claimed nucleic acid molecules lack utility apparently because one would allegedly not be able to recognize an appropriate ATG codon or ORF for the claimed nucleic acid molecules. *See* Office Action at pages 3-4. However, as stated above, one of ordinary skill on the art would clearly be able to ascertain these elements based on Applicants' disclosure (*see, e.g.*, specification at page 149, lines 16-18) and tools available to practitioners in the art, *e.g.*, BLASTX. Moreover, the specification discloses that the nucleic acid molecules of the present invention encode phosphogluconate pathway enzymes or fragments thereof. Therefore, an ORF or start codon is not necessary for the claimed nucleic acid molecules.

An examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific

reasoning to rebut such as assertion.” Federal Register 66(4):1096, Utility Guidelines (2001). “[A] ‘rigorous correlation’ need not be shown in order to establish practical utility; ‘reasonable correlation’ is sufficient.” *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996). “An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof.” M.P.E.P. § 2107.03, at page 2100-43. Applicants have demonstrated such a reasonable correlation.

The claimed nucleic acid molecules have been asserted to encode maize or soybean phosphogluconate pathway enzymes or fragments thereof. The specification provides ample correlation between the claimed nucleic acid molecules and phosphogluconate pathway proteins. Accordingly, the assertion of the use of the claimed nucleic acid molecules to encode phosphogluconate pathway enzymes or fragments thereof satisfies the utility requirement of 35 U.S.C. § 101.

The Examiner has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. To the contrary, the Examiner has acknowledged that “[i]t is possible that a claimed SEQ ID NO: encodes a fragment of an enzyme.” Office Action at page 3. Applicants have thus provided sufficient evidence to lead a person of ordinary skill in the art to conclude that the asserted utilities are more likely than not true.

Applicants have disclosed a specific, substantial and credible utility for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35

U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

### **III. Rejection under 35 U.S.C. § 112, first paragraph, Enablement**

Claims 1-2, 10-13, 15-22 and 24-31 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 4. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

Claims 1, 22, 24 and 28 also stand rejected under 35 U.S.C. § 112, first paragraph, as the claimed subject matter allegedly is “not described in the specification in such a way as to enable one skilled in the art... to make or use the invention.” Applicants respectfully maintain their traversal this rejection.

The Examiner maintains that “[a]s one skilled in the art would not know how to use the inventive nucleic acid sequences to make the particular enzymes recited in the claims for the reasons previously set forth, the claims are not enabled.” Office Action dated December 2, 2004 at page 6. The Examiner also maintains that homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence. *Id.* at pages 5-7<sup>1</sup>. While the Examiner has admitted that the specification discloses that the claimed nucleic acid sequences

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<sup>1</sup> Applicants note that the Examiner appears to incorporate the rejections as previously stated by noting that for “reasons set forth in the previous office action” the rejection is maintained Office Action at page 5.

encode the recited enzymes, Office Action mailed June 17, 2003 at page 7, the Examiner maintains that the specification “does not disclose anywhere that the claimed nucleic acids actually encode any peptide or protein.” *Id.*

Applicants maintain their disagreement with these assertions. In addition, as previously argued, Applicants respectfully point out that the claims are directed to nucleic acid molecules, not enzymes as alleged by the Examiner. Furthermore, Applicants assert that an analysis of the criteria presented by *In re Wands* supports Applicants’ position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The “make-and-test” quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, expression systems, and enzyme assay conditions, to which a person of ordinary skill in the art has access. The Examiner asserts that undue experimentation would be required to practice the claimed invention. Office Action dated December 2, 2004 at page 6. However, one skilled in the art is sufficiently guided by Applicants’ disclosure, which sets forth nucleic acid molecules as well as the enzymes or fragments thereof encoded by the nucleic acid molecules.

The previous action further asserts that the specification does not disclose any ORFs and therefore is not enabled. Office Action dated December 2, 2004 at page 6. As stated above, practitioners in the art are guided by the high level of skill in the art and the present disclosure of the specification (*see, e.g.*, specification at page 110, lines 1-11). Performing routine and well-known steps, such as sequence alignment protocols, ORF identification, and known enzyme



assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides evidence of sequence identity, discloses construct preparation, and discusses the use of the claimed SEQ ID NOs to isolate additional sequences within a genome. *See, e.g.*, Examples 1-4, the sequence listing and Table A. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth, and sixth *Wands* criteria focuses on the nature of the invention, the state of the art, and the relative skill in the art. The Examiner acknowledges the high level of skill in the art. Office Action dated June 7, 2003 at page 8. The specification provides a detailed description of the nucleic acid sequences required by the claims, and further describes amino acid sequences derived there from, and constructs and methods of use related thereto. *See, e.g.*, specification at page 46, line 6 through page 52, line 16 (describing polypeptide molecules encoded by the nucleic acid sequences of the present invention, homologues and other modifications, and methods of producing or expressing peptides or fragments of peptides), and page 92, line 1 through page 114, line 5 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm, and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner admits “that identification of ORFs and peptide synthesis [is] fairly routine”. Office Action dated December

2, 2004 at page 6. The specification further discloses sufficient guidance to render the results of substitutions, additions, and deletions within the claimed nucleic acid molecules predictable. *See, e.g.*, specification at page 8, line 21 through page 13, line 21, page 48, line 6 through page 50, line 6 and page 149, line 10 through page 152, line 9. Furthermore, the specification provides sufficient guidance to one of skill in the art to decipher the information necessary to make and use the claimed nucleic acid molecules. *See, e.g.*, specification at page 149, line 10 through page 150, line 9 (describing software that can be used to identify open reading frames within the claimed nucleic acid molecules), and page 110, lines 1-11 (citing references to develop assays for gene expression).

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure “adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility”. *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein.” *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original).

The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the nucleic acid molecules of claims 1, 22, 24 and 28. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement). Therefore, because the above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the Examples, and the claims, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (“the enablement requirement is met if the description enables any mode of making and using the invention”) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

#### **IV. Rejection under 35 U.S.C. § 112, first paragraph, Written Description**

Claims 1, 11-13, 15-22, 24 and 27-30 are again rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action at page 5. Applicants respectfully traverse this rejection.

The Examiner, acknowledging that “[s]equences consisting of SEQ ID NOs 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description requirement,” does not dispute that Applicants had possession of and have adequately described the claimed SEQ ID NOs. Office

Action at pages 5-6. However, the Examiner argues that “with the exception of sequence consisting of SEQ ID NOs 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides.” *Id.* At pages 6-7.

One of the Examiner’s bases for this rejection is that the rejected claims “recite open claim language (comprising).” *Id.* at page 6. As Applicants have previously set forth, this argument conflicts with existing patent jurisprudence. It is well-established law that use of the transitional term “comprising” leaves the claims “open for the inclusion of unspecified ingredients even in major amounts.” *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of “unspecified ingredients” is that they are not specified or described. The Examiner attempts to turn the legal meaning of “comprising” on its head by requiring Applicants to describe hypothetical claim elements. Applicants maintain that the claims as amended recite the required nucleic acid sequences, define the enzyme or fragment thereof encoded by the sequences, and recite hybridization parameters. Applicants have described the claimed invention.

Applicants reiterate that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37

U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, complements and variations thereof, sequences that hybridize to the claimed nucleic acid molecules under the recited conditions, as well as the enzymes, or fragments thereof, they encode. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.*, specification at page 23, line 12 through page 26, line 20; page 46, line 6 through page 48, line 5; page 53, line 10 through page 54, line 22; and page 65, line 21 through page 74, line 18). The specification also describes appropriate hybridization conditions (*see, e.g.*, specification at 43, line 13 through page 45, line 4); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 48, line 6 through page 50, line 6); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 59, lines 4-15); plant homologue proteins (*see, e.g.*, specification at page 59, line 16 through page 60, line 6); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.*, specification at page 87, line 12 through page 89, line 3); vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.*, specification 93, line 1 through page 107, line 19); and construc-

tion of cDNA libraries using the claimed nucleic acid molecules (*see, e.g.*, specification at page 152, line 13 through page 222, line 7 (Examples 1-3)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "with the exception of sequences consisting of SEQ ID NOs 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". Office Action at pages 6-7. The Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. This assertion is unfounded. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genera from non-members.

Applicants maintain that they have provided a representative number of detailed chemical structures, i.e., the nucleic acid sequences of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, and their complements, as well as recited specific hybridization conditions. The common structural feature (the nucleotide sequence of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 and their complements) is shared by every nucleic acid molecule in the claimed genera, and this feature distinguishes members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1,

then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.<sup>2</sup> If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. Accordingly, the standard elucidated in *Lilly* for the written description requirement has been met.

Furthermore, nucleic acid molecules within the scope of the instant claims are also readily identifiable as they either encode a maize or soybean phosphogluconate pathway enzyme or fragment thereof or they do not. Claims 1-2, 22, 24, and 25 are directed to “substantially purified nucleic acid molecules that encode a maize or soybean” phosphogluconate pathway enzyme or fragment thereof. Applicants respectfully maintain that the present specification complies with the written description requirement by describing nucleic acid sequences that encode maize or soybean phosphogluconate pathway enzymes or fragments thereof. *See, e.g.*, Table A. Descriptions of ORFs are not required to comply with the written description requirement.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed inven-

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<sup>2</sup> The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA comprises the nucleotide sequence of SEQ ID NO: 4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4. *See, e.g.*, claim 13.

tion with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. Moreover, the Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed. “A general allegation of ‘unpredictability in the art’ is not a sufficient reason to support a rejection for lack of adequate written description.” MPEP § 2163 at 2100-170.

For these same reasons, the Examiner’s rejection of claims 1, 22, 24 and 25 for lack of adequate written description, *see* Office Action at page 11, must also fail as it too overreaches the requirements of the law. Simply put, Applicants have described the invention encompassed by the claims. No more is required.

The Examiner has offered no evidence to demonstrate, in light of Applicants’ disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants’ has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.



## **V. Non-Statutory Double Patenting Rejections**

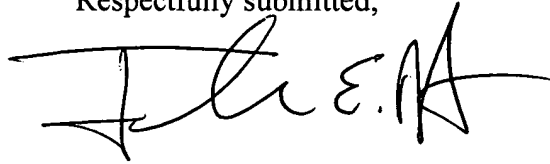
Claims 1, 11, 16, 29, and 31 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,114 (the '114 Application). Applicants note that the rejection is provisional because no allegedly conflicting claims have been patented. Upon an indication of allowable subject matter, a terminal disclaimer with regard to any issued claims in the '114 Application will be filed. At that time, withdrawal of this rejection is respectfully requested.

Claims 1, 11, 16, 29, and 31 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,115 (the '115 Application). Applicants note that the rejection is provisional because no allegedly conflicting claims have been patented. Upon an indication of allowable subject matter, a terminal disclaimer with regard to any issued claims in the '115 Application will be filed. At that time, withdrawal of this rejection is respectfully requested.

**Conclusion**

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "T. E. H. & D. R. M.", written over a horizontal line.

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